

# Non-interventional, post-authorization safety study (PASS) of patients treated with commercially available liso-cel (lisocabtagene maraleucel) for large B-cell lymphomas (JCAR017-BCM-005)

**First published:** 20/03/2023

**Last updated:** 02/07/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS103855

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### Study ID

103856

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### DARWIN EU® study

No

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### Study countries

 Austria

 Belgium

-  Croatia
  -  Czechia
  -  Denmark
  -  Finland
  -  France
  -  Germany
  -  Greece
  -  Italy
  -  Netherlands
  -  Norway
  -  Poland
  -  Portugal
  -  Spain
  -  Sweden
  -  Switzerland
  -  United Kingdom
  -  United States
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### **Study description**

The purpose of this PASS is to further characterize the safety profile of liso-cel in the postmarketing setting. This study will include patients from existing independent registries, such as, but not limited to, the European Society for Blood and Marrow Transplantation (EBMT) and the Center for International Blood and Marrow Transplant Research (CIBMTR). The JCAR017-BCM-005 study will be part of the overall liso-cel Risk Management Plan (RMP) including any required regional Pharmacovigilance Plan (PVP) outside the European Union (EU).

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### **Study status**

Ongoing

## Research institutions and networks

## Institutions

### Bristol-Myers Squibb (BMS)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

### Center for International Blood and Marrow Transplant Research (CIBMTR)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

### CIBMTR United States

## Networks

### EBMT

## Contact details

### **Study institution contact**

Transparency and Disclosure Lead [ctt.group@bms.com](mailto:ctt.group@bms.com)

**Study contact**

[ctt.group@bms.com](mailto:ctt.group@bms.com)

### **Primary lead investigator**

Montserrat Miret

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 18/08/2022

Actual: 18/08/2022

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### **Study start date**

Planned: 18/03/2023

Actual: 17/03/2023

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### **Data analysis start date**

Planned: 18/03/2023

Actual: 17/03/2023

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### **Date of interim report, if expected**

Planned: 04/02/2028

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### **Date of final study report**

Planned: 31/12/2043

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bristol-Myers Squibb

## Study protocol

[jcar017-bcm-005-pass-prot 30-aug-2022-redacted-v2.pdf](#) (736.05 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 1 (imposed as condition of marketing authorisation)

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### **Regulatory procedure number**

EMA/H/C/PSP/S/0098.1

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

The main objective is to the incidence and severity of selected adverse drug reactions (ADRs), as outlined in the Summary of Product Characteristics (SmPC), in patients treated with liso-cel in the postmarketing setting and to monitor for potential clinically important adverse events (AEs) that have not yet been identified as part of the liso-cel safety profile.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

BREYANZI

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**Medical condition to be studied**

Follicular lymphoma

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**Additional medical condition(s)**

relapsed/refractory diffuse large B-cell lymphoma, primary mediastinal B-cell lymphoma

## Population studied

### Age groups

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### Estimated number of subjects

750

## Study design details

### Outcomes

Secondary malignancies Cytokine release syndrome (CRS) all grades  
Neurotoxicities all grades Prolonged cytopenias Pregnancy outcome Other AEs considered related to liso-cel treatment (Grade  $\geq$  3, where applicable), Overall response rate (ORR) Complete response rate (CRR) Duration of response (DoR) Progression-free survival (PFS) Overall survival (OS) Time to next treatment (TTNT)

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### Data analysis plan

Results will be analyzed and reported descriptively and no formal hypothesis testing is intended. Summary statistics will consist of the number and percentage of patients in each category for discrete variables, whereas for

continuous variables the sample size, mean, median, standard deviation, minimum, and maximum will be given. For the primary safety endpoints, incidence proportions and incidence rates will be calculated with the appropriate time periods and methods, analyses will be carried out both with and without accounting for competing risks. For the secondary effectiveness endpoints, Kaplan-Meier estimates and curves will be generated.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### Data sources

#### **Data source(s), other**

CIBMTR United States, EBMT

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#### **Data sources (types)**

[Other](#)

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#### **Data sources (types), other**

Prospective patient-based data collection

### Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No